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VIA HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

RE: Docket No. 98N-0359

To Whom It May Concern:

The Enzyme Technical Association ("ETA") respectfully submits these comments, in duplicate, in response to the Food and Drug Administration's ("FDA's") Notice entitled "Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments." 64 Fed. Reg. 47845 (September 1, 1999) (the "Notice"). ETA is a trade association composed of the majority of enzyme manufacturers and distributors in the United States. As such, ETA members are directly affected by the program priority decisions that currently face the FDA's Center for Food Safety and Applied Nutrition ("CFSAN").

ETA submitted comments to this docket last year following a similar request for comments on CFSAN's program priorities. See 63 Fed. Reg. 30242 (June 3, 1998). ETA also took advantage of an opportunity to present its suggestions at a public meeting that was held in July of last year. We were pleased to note that CFSAN has since taken action with respect to ETA's suggestion to renew funding for the Food Chemicals Codex ("FCC") and has taken partial action with respect to our request that the Generally Recognized as Safe ("GRAS") Affirmation Petition 3G0016 ("GRASP 16") be completed. We applaud the agency for its decision to fund a resource as valuable as the FCC and for the steps that have been taken to complete GRASP 16. ETA also appreciates CFSAN's willingness to seek and give serious consideration to comments submitted to this docket suggesting specific program priorities.

98N-0359 C34

These comments address each of the questions presented by the FDA in the Notice. Additionally, we have provided an in depth discussion of three specific areas that demand CFSAN's immediate attention and provide the Center with an opportunity to complete a program that will benefit both the public and the food industry. These areas are: (1) the GRAS Notification procedure; (2) the Biotechnology Final Consultation procedure; and (3) completion of GRASP 16.

I. FDA's SPECIFIC QUESTIONS

A. With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?

Yes. As noted below, ETA believes that the failure of the GRAS affirmation petition process presents a consumer safety issue. The current system results in an inefficient misdirection of resources that otherwise could be directed to public safety issues. Furthermore, the GRAS notification procedure would encourage manufacturers to notify FDA of their GRAS determinations. This would increase the agency's knowledge of products in the marketplace.

B. Within the 10 program areas identified previously, what specific activities do you believe should be top priorities for CFSAN and why?

The following areas demand immediate attention from CFSAN: (1) completion of GRASP 16; (2) completion of the GRAS notification regulation; and (3) continuation of the biotechnology final consultation procedure. The basis for our recommendations is provided in our detailed discussion below.

C. FDA needs to ensure that its research programs provide the scientific information upon which regulatory decisions are made. In CFSAN, what do you believe should be the highest priority areas for conducting research?

ETA believes that biotechnology is important for the continued development and improvement of safe food and food ingredients. FDA must invest its resources to maintain expertise in food biotechnology and thereby support sound science based on regulatory decisions and encourage future advances in this vital area of the food industry.

D. Because so much of our nation's food supply is either imported or exported, what do you believe should be the highest priority international activities? Please identify specific activities in your answer.

CFSAN cannot ignore the importance of the international marketplace. The United States has become heavily dependent upon both imports and exports of food products. CFSAN has taken a major step towards supporting its international activities by renewing support for the Food Chemicals Codex. However, ETA believes that CFSAN can significantly improve its support for the center's international activities by finalizing the GRAS Notification procedure. As noted in our detailed comments, the current GRAS affirmation procedure is negatively impacting on the international marketplace.

II. DETAILED COMMENTS

A. GRAS Notification Procedure

We applaud CFSAN's decision to place the completion of the GRAS Notification regulation on the center's "A List" (i.e., projects which CFSAN is committed to completing by the end of 1999) for 1999. However, in the event that CFSAN is unsuccessful in its attempts to complete the GRAS notification process by the end of this year, the completion of this vital program needs to be a "top priority" for 2000. CFSAN needs to move forward on this important regulation.

GRASP 16 is demonstrative of the dismal failure that the GRAS affirmation petition has become. The current system discourages the development of new products and hinders FDA's ability to monitor the nation's food supply. The resource-intensive GRAS petition process needs to be replaced with the more streamlined notification system so that vital agency resources can be redirected to address food issues that are a priority with respect to public health protection. See 62 Fed. Reg. at 18941. Likewise, a simpler, more effective, GRAS notification system would provide an incentive for manufacturers to inform FDA of their GRAS determinations. This would improve FDA's ability to ensure safer foods by increasing the agency's awareness of the composition of the nation's food supply and the cumulative dietary exposure to GRAS substances. See id.

The international marketplace is hit particularly hard by the failure of the current GRAS affirmation process. Marketing pressures make it very difficult for

manufacturers to globally market products that have been self affirmed as GRAS and, as noted above, waiting for FDA affirmation of GRAS status is not an acceptable alternative.

Additionally, the GRAS notification system could assist other federal agencies that review the safety of food substances. For example, the Bureau of Alcohol, Tobacco and Firearms ("BATF") and the United States Department of Agriculture ("USDA") routinely rely on prior FDA determinations when reviewing the safety of food substances subject to these agencies' jurisdictions. Both the USDA and BATF normally require a specific FDA regulation (GRAS or food additive) or an FDA advisory opinion before they will accept a substance for a regulated use. FDA could streamline this process by consulting with BATF and USDA to ensure that those agencies understand and are in agreement with the GRAS notification procedure and by confirming that the procedure provides a means by which those agencies may accept substances which are the subject of GRAS notifications.

CFSAN could remedy many of the failures of the current GRAS affirmation process by finalizing a GRAS notification regulation so that there would be a public statement of FDA's acceptance of a GRAS notification. Furthermore, finalizing the regulation is feasible, desired by a majority of the food industry, and provides an opportunity for CFSAN to eliminate an obviously inefficient regulatory scheme.

B. Biotechnology Final Consultation Procedure

In stark contrast to the GRAS affirmation petition procedure, the FDA's policy on food biotechnology has been very successful. CFSAN should continue this successful program in its current form. The FDA, along with several other federal agencies, first adopted a formal biotechnology policy in 1986. 51 Fed. Reg. 23302 (June 26, 1986). In 1992, the agency refined its policy as it applied to biotechnology derived plants. 57 Fed. Reg. 22984 (May 29, 1992). Since 1994, developers of biotechnology derived food products have been encouraged to submit summaries of safety and nutritional assessments to the FDA. The FDA, after "consulting" with the developer, then publishes the name and brief description of the product on the agency's Internet website. This refreshing use of new technology serves the interests of all concerned parties: the public, FDA, and developers of biotechnology products.

The final consultation process ensures that FDA is kept abreast of developing new biotechnology products. In turn, manufacturers receive some benefit by having their product identified on the FDA website as having successfully completed "final consultation." The public benefits by FDA's increased knowledge of the marketplace and through access to new product information. As we noted above, we believe that this system of disclosure should be a model for the GRAS notification procedure.

We recognize that it may seem odd to ask for the maintenance of a procedure rather than a specific change or implementation. However, we believe our comments regarding biotechnology are timely in light of the extensive and organized opposition to biotechnology. See e.g., Alliance for Bio-Integrity v. Shalala, No. 98-CV-1300 (D.D.C. filed May 28, 1998) (seeking special labeling for genetically modified foods). FDA continues to face increasing pressure in the form of lawsuits and slanted news reports to change its biotechnology policy. However, the basis for these arguments is emotional rather than scientific. FDA has correctly determined that, with proper safeguards, biotechnology can contribute to the continued development and improvement of safe food and food ingredients. ETA urges FDA to continue its current policy of monitoring biotechnology derived foods through the final consultation procedure.

C. GRAS Affirmation Petition 3G0016

CFSAN should conclude its review of GRASP 16. See 38 Fed. Reg. 9,256 (Apr. 12, 1973); 38 Fed. Reg. 15,471 (June 12, 1973); 49 Fed. Reg. 34,305 (Aug. 29, 1984); 52 Fed. Reg. 23,607 (June 23, 1987); 58 Fed. Reg. 48,889 (Sept. 20, 1993); 61 Fed. Reg. 40,648 (Aug. 5, 1996) (collectively, "GRASP 16"). The petition seeks GRAS affirmation for a significant number of enzymes that are used in food products. Although the petition was accepted for filing by FDA over 25 years ago, the FDA has yet to complete the review of the petition. 38 Fed. Reg. 9,256.

While the GRASP 16 enzymes from animal, plant and *Bacillus* sources have been affirmed as GRAS (See 60 Fed. Reg. 32904 (June 6, 1995), and 64 Fed. Reg. 19887 (April 23, 1999)), the fate of the remaining enzymes remains uncertain despite the relative ease with which the matter could be resolved. While we thank CFSAN for its recent publication of a final rule on the *Bacillus* derived enzymes, a major step in the completion of GRASP 16 remains to be completed. As required by 21 C.F.R. § 170.35, GRASP 16 provided substantial data to support the historical use and therefore the safety of the GRASP 16 enzymes. Furthermore, because FDA

has had 25 years to review this information, any safety concerns relating to these enzymes have been resolved long ago. Therefore, FDA has merely to publish the GRAS affirmation final order and regulation for the remaining enzymes in order to complete this 25 year project.

We understand that CFSAN is seeking to focus on a few projects that can be accomplished in a definite period of time rather than continuing to pursue numerous projects, none of which ever seem to reach completion. The review of GRASP 16 presents an opportunity to put this new approach into action. The review can be completed rather quickly and at a low cost to the agency. Furthermore, because the GRASP 16 petition is the linchpin for much of the food biotechnology industry, completing the review would have immediate and significant positive impact on the food industry.

In closing, ETA appreciates the opportunity to comment on the Notice and supports the Center's decision to involve the public in its priority making decisions. If you have any questions concerning these comments please contact me.

Sincerely,

Nancy Zeman by mail

Nancy Zeman
Chair, Enzyme Technical Association